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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,062	09/26/2000	Bradley J. Wessman	20000389.ORI	5103

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EXAMINER	
ART UNIT	PAPER NUMBER
3762	28

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/670,062	WESSMAN, BRADLEY J.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/5, 3/4 & 3/8/04 (Amendment, RCE, IDS)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *27*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 3/4/04 has been entered.

2. The Applicant amended the claims to overcome the rejection of record hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 112

3. Claims 9-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner finds discussion of multiple welds associated with figures 4 and 5 (Specification page 8 starting at line 18), but the Examiner is unable to find the limitation of independent claim 9, "the band welded to the distal end" being outside the welding region. New matter may not be entered at this point in the prosecution. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. Claims 1-3, 5-8 and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Winkler (US 5417208). Winkler discloses an electrode-carrying catheter with a conductor (45), a conductive pad/ elongate conductive element (51) and a ring electrode (53) (figure 2, figures 4A-4D and figure 6). The ring electrode (53) has projections extending from the inner wall of the lumen (figures 6 and 7). The conductor and copper conductive pad have a welded connection (col. 6 @ 51-59).

As to claims 1 and 30 and a conductive pad within a welding region and a band welded to the conductive pad to electrically connect the band to the conductor / proximal end of the conductor, Winkler teaches a copper ribbon conductive pad (51) joined by welding within a welding region (figures 4A-4D; figure 6; col. 3 @ 20-26), and a band (53) welded (c 8, ll 8-9) to the conductive pad (51) to electrically connect the band (53) to the conductor (45) / proximal end of the conductor (one conductor is provided for each electrode with the proximal end of the conductor being connected to the electrode) (col. 5 @ 17-21; col. 2 @ 30-36).

As to claims 1 and 30 and the insulation being removed to expose a portion of the conductor, Winkler teaches the insulation is removed to form a window (47) to expose the conductor/ wire and if necessary removes the insulation from the conductor to expose the conductive wire (figures 4A-4D and 7; col. 6 @ 6-22).

As to claims 1, 9 and 30 and the band being welded to the conductive pad within the welding region, the welding region is defined by an area where the insulating material is removed to expose at least a portion of the at least one conductor, hence the welding region in Winkler, as view in figures 6 and 7, includes the area where the hard core layer

(20), the soft layer (44) and the conductor insulation (45) is removed. As shown in figures 6 and 7, the band impacts the welding region and is secured by welding (col. 8 @ 8-9); it is inherent the sensitive interface of the supported and unsupported band would be fortified with a weld, the location of this weld being in the welding region.

As to claim 9, as shown in figures 6 and 7, the elongate element (51) has a proximal end located against the soft insulation (44) on the right side of figure 7, and has a distal end contacting the band (53) located on the left side of figure 7, hence the proximal and distal ends of the of the elongate element are electrically connected to the conductor within the welding region. In addition, the band is secured by welding (col. 8 @ 8-9); inherently the sensitive interface of the supported and unsupported band would be fortified with a weld that would attach the distal end of the elongate element to the band by a weld.

As to claims 1-8 and a medical lead where the insulator includes at least one welding region formed by removal of the at least a portion of the insulator, the welding region formed to expose at least a portion of the at least one conductor, with the band welded to the conductive pad at the welding region, Winkler teaches a medical lead (10) wherein the insulator (21) includes at least one welding region (including window 47 – figure 4A) formed by removal of the at least a portion of the insulator, the welding region formed to expose at least a portion of the at least one conductor (45 - figure 4A) (col. 6 @ 6-10 and 51-60), with the band (53 - figure 6) welded to the conductive pad (51 - figures 4C and 6) at the welding region (col. 8 @ 8-9).

As to claims 9-17 and an elongated conductive element with a proximal end electrically connected to the conductor and a distal end welded to the band, the elongate

element (51) has a proximal and a distal end. The proximal end (51a –figure 7) is connected to the conductor (45 – figure 7) within the welding region (including window 47 – figure 4A) hence electrically connecting the conductor and the elongate element. The distal end (51c - figure 7) is welded to the band (53 – figures 6 and 7). As previously discussed the band is secured by welding (col. 8 @ 8-9); inherently the sensitive interface of the supported and unsupported band would be fortified with a weld that would attach the distal end of the elongate element to the band by a weld.

As to claims 30-32 and a lead where the insulator includes at least one welding region defined by a groove formed in the insulator to expose at least a portion of the at least one conductor, with the band welded to the conductive pad at the welding region to electrically connect the band to the conductor, Winkler teaches a lead (10) where the insulator (21) includes at least one welding region (including window 47 - figure 4A) defined by a groove (47) formed in the insulator to expose at least a portion of the at least one conductor (45 – figure 4A), with the band (53 – figure 6) welded (col. 8 @ 8-9) to the conductive pad (51 – figures 4C and 6) at the welding region to electrically connect the band to the conductor.

As to claims 1 and 30 and "one welding region formed by removal of at least a portion of the insulator", Winkler teaches a welding region created by removing a portion/ groove of the insulator to create a window (figure 4A - 47) that exposes an area of the conductor (col. 6 @ 33-38).

The Applicant's arguments filed 1/5/04 have been fully considered, but they are not convincing. The Applicant argues in independent claims 1 and 30, Winkler does not

teach "the band welded to the conductive pad at the welding region" because of the gap between the pad (51) and the electrode (53) (as shown in figure 7). The Examiner disagrees. Winkler teaches the electrode (53) is uniformly crimped and welded to the pad (51) (col. 7 @ 23 - col 8 @ 16). The weld connecting the pad (51) and electrode (53) is located in the welding region, the welding region read to be the area where the insulating material is removed to expose at least a portion of the at least one conductor. While the weld between the pad and the electrode in the welding region is not a continuous weld, as indicated by the gap between pad (51) and electrode (53) in figure 7, a weld is formed between the pad (51) and the electrode (53) in the outer areas of the welding region at the beginning and at the end of the gap between the pad (51) and the electrode (53) (figure 7), hence teaching "the band is welded to the conductive pad at the welding region". The rejection of record stands.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 4, 13 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler. As discussed in paragraph 4 of this action, Winkler discloses the claimed invention except for the pad/ conductive element being attached to the conductor by crimping or an adhesive.

Winkler teaches attaching the pad/ conductive element to the conductor using welding to secure the connection between the two metal components (figures 4A-4D & 6; col. 3@ 20-26). It is well known in the lead fabrication art that metal components can be attached by welding, crimping and/or adhesives. Absent any teaching or criticality or unexpected results, merely changing the method used to securely connect the metal components from welding to crimping or adhesives would be an obvious design choice. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used crimping or welding in the Winkler system in order to provide a secure electrical connection between the pad/ conductive element and conductor that meets the design needs to ensure reliable performance of the device. (Instant Specification page 3, lines 16-18: "The elongated conductive element may be electrically connected to the conductor by welding, conductive adhesive, crimping or other methods".)

7. Claims 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler (US 5417208) in view of Baudino et al. (US 5458629). As discussed in paragraph 4 and 6 of this action, Winkler discloses the claimed invention except for the band welded to the distal end outside the welding region.

Baudino et al. teach lead fabrication using multiple welds for the purpose of securing the electrode to the lead. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used multiple welds outside the welding region including welds of the distal end outside the welding region in the Winkler system in order to provide a cost effective lead with a secure electrical connection to ensure long dependable operation of the lead (col. 2@ 56 – col. 3 @ 16).

Specification

8. The amendment filed 1/5/04 is objected to under 35 U.S.C. 132 because it appears to introduce new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Independent claim 9, "the band welded to the distal end" being outside the welding region.

Applicant is required to cancel the new matter in the reply to this Office Action.

Statutory Basis

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, telephone number (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
5/16/04

Angela D. Sykes

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